Supreme Court, U.S.
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No. 90-1898

IN THE
Supreme Court of the United States
OCTOBER TERM, 1991

ABBOTT LABORATORIES,
Petitioner,

v.

DAVID A. KESSLER, M.D., COMMISSIONER,
Respondent.

Petition for Writ of Certiorari to the United States Court of Appeals for the District of Columbia Circuit

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REPLY BRIEF FOR PETITIONER

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REPLY BRIEF FOR PETITIONER

Respondent's Opposition to the Petition for Certiorari represents an abrupt about-face on the issues that the parties had considered dispositive throughout this litigation, and fails to diminish either the significance of this case or the appropriateness of further review by this Court.

I. REVIEW OF THE COURT OF APPEALS' DECISION IS APPROPRIATE AT THIS TIME

Respondent's primary contention is that further review of this case is unnecessary because the court of appeals' decision is "essentially interlocutory." Opp. 9. Whatever this mock-procedural phrase means, the contention has no merit. If Respondent is suggesting that the issues in this case are unripe and subject to further judicial consideration, then Respondent is wrong. The decision of the

court of appeals, of course, is not interlocutory but quite final. And any subsequent litigation over the market exclusivity provisions will have to address the decision for which review is now sought.

Nor is the decision of the court of appeals "essentially" interlocutory. It not only terminates this litigation but settles, finally and conclusively, every one of the very significant statutory and constitutional issues that Petitioner has brought before this Court. Respondent suggests on the contrary that, on remand, it is free to adopt the statutory construction suggested by the court of appeals "or some other reading that the agency might develop upon further consideration."[1] Opp. 10. No construction consistent with the court of appeals' opinion, however, can accord Abbott its rights under the Hatch-Waxman Amendments, because the court of appeals has *held* that DEPAKOTE cannot rationally be accorded ten years' market exclusivity.[2] So far as refusing to implement unambiguous statutory language, depriving Abbott of its statutory rights, and overruling Congress' legislative prerogatives are concerned, the court of appeals' decision is as final as it will ever be. And this is the proper time at which to review it.

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[1] Respondent's suggestion of its relative freedom in construing the statute is illusory, and no language comparable to that just quoted is to be found in the court's opinion. Indeed, the court rejected the statute's plain meaning (and Respondent's construction) in favor of a single alternative that, alone, caused the statute in its view to be ambiguous. A reading of the pertinent language of the court's opinion makes evident that Respondent has no real discretion in construing the statute. *See* Pet. App. 7a-8a.

[2] Respondent makes a passing suggestion that the court of appeals' rejection of Petitioner's plain meaning construction is dicta, suggesting that it was "not necessary to the court's decision." Opp. 13. The court, however, could not have been clearer in its holding that the construction was unreasonable and could not lawfully be adopted by Respondent. *See* Pet. App. 11a.

II. RESPONDENT'S DEFENSE OF THE COURT OF APPEALS' DECISION IS UNAVAILING

As stated earlier, Respondent does not demean the significance of the issues presented in this case, acknowledging that at stake is the meaning of "major changes in the law concerning approval and marketing of new drugs" effected by the Hatch-Waxman Amendments. Opp. 2. Rather, Respondent opposes the Petition For Certiorari by defending the conclusion of the court of appeals that Respondent's own prior construction of the statute was unreasonable.

The centerpiece of this quiet but remarkable about-face is the assertion that, because different constructions have been given to the market exclusivity provisions by different parties, the statute simply must be ambiguous. "That diversity of interpretation alone belies petitioner's claim of statutory clarity and explicit congressional intent . . . ." Op. 11. While this certainly is a democratic and open-minded approach to statutory construction, it is not the law, and is a remarkably unprincipled one to see urged by the Solicitor General.[3] And on its face it proves nothing: There has been absolutely no dispute as to the alleged ambiguity on which the court of appeals majority based its decision. No one—no court, no party, no agency, and no counsel—had, after years of study, ever so much as suggested the construction pulled out of thin air by the court of appeals and now defended by Respondent with such zest.

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[3] Respondent cites no case support for its novel theory, and Petitioner has found none. Indeed, instances abound in which this Court has declared unambiguous a statute whose meaning was hotly debated. *See, e.g., Burlington Northern R. Co.* v. *Oklahoma Tax Comm'n*, 481 U.S. 454 (1987) (Court finds statute unambiguous, rejecting differing contrary interpretations of court of appeals and respondents); *United States* v. *James*, 478 U.S. 597 (1986) (Court finds statute unambiguous, reversing *en banc* court of appeals that had reversed panel and district court).

But far more important is the reason *why* Respondent and the court of appeals have strained the law and the English language to avoid the statute's plain meaning. Both simply and impermissibly have disagreed with the line drawn by Congress in distinguishing ten-year and two-year market exclusivity, and have concocted one excuse after another to substitute their judgment for that of the duly elected legislature. The court of appeals, whose decision is before this Court, speculated that in some cases the statute's plain language would not advance the statute's purpose, wrongly claiming (in a charge parroted by Respondent) that Petitioner effectively conceded the point.[4] Upon this finding the court based its refusal to honor the language as written, and in so doing made an error of constitutional dimension.

Respondent answers by announcing: "Certainly no one, least of all the court of appeals, has suggested that the exclusivity provisions are invalid." Op. 12. But that is precisely what the court of appeals did, by holding that the statute as written is unenforceable because the court could not understand its purpose. Such judicial nullification unconstitutionally invades the legislative province. It also has the very practical effect of calling into question the enforceability of all legislation whose precise contours are fashioned by Congress not so much by principle as by compromise.

Legislation involves line-drawing. That quintessential policy judgment is for Congress to make and is not for a court to undo because it cannot fathom why Congress

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[4] *See* Opp. 13, Pet. App. 10a. Petitioner has in fact consistently supported the plain language of the market exclusivity provisions, believing it to reflect the realities of the process by which new drugs typically are developed for market. *See, e.g.*, Brief of Appellant Abbott Laboratories (D.C. Cir.) 23 n.13. The U.S. District Court for the Eastern District of Virginia reached the same conclusion in the *Glaxo* litigation. *See Glaxo Operations UK, Ltd.* v. *Quigg*, 706 F. Supp. 1224, 1229-30 n.12 (E.D. Va. 1990), *aff'd*, 894 F.2d 392 (Fed. Cir. 1990).

drew its lines precisely where it did, or because it may believe the legislative classification to be overinclusive or underinclusive. This case is about such a judicial hijacking of the legislative function, and that is why the court of appeals' refusal to accept the limitations of its role is a wrong and dangerous precedent.

III. THE DECISION OF THE COURT OF APPEALS CONFLICTS WITH THE DECISION OF THE FEDERAL CIRCUIT IN *GLAXO*

Respondent advances two arguments to minimize the significance of the conflicting decision of the Federal Circuit in *Glaxo Operations UK Ltd.* v. *Quigg*, 894 F.2d 392 (Fed. Cir. 1990). First, "and of greatest importance," Respondent contends that the decision should be of no importance whatsoever to this Court because *Glaxo* involved "somewhat different" language found in a different section of the Hatch-Waxman Amendments. Opp. 9-10. In the court of appeals, however, Respondent quite rightly construed what it termed the "almost identical" language of the two sections *in para materia*, and argued simply that the Federal Circuit had "fundamentally erred" by adopting the plain-meaning construction urged by Petitioner here. *See* Brief for Appellee (D.C. Cir.) at 20-21. Respondent also cites in this regard the suggestion of the court of appeals majority that even the same language could have different meanings in different parts of a statute.[5] True, perhaps, as a remote possibility in some cases, but not as a general rule, and not in this case. The common language of the two sections at issue here simply *cannot* be construed differently: It is, indeed, unambiguous.

Second, Respondent makes the puzzling suggestion that this case and *Glaxo* are not in conflict because the Com-

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[5] The court of appeals in fact was referring to the term "active ingredient," which is not the source of the alleged ambiguity here. *See* Pet. 13.

missioner of Food and Drugs implements the market exclusivity provisions, while the Commissioner of Patents and Trademarks construes the patent term extension provisions. Opp. 10-11. On the contrary, the very fact that there is not one administrator to take responsibility for ensuring uniformity in the statutory scheme makes review by this Court all the more urgent. Congress crafted unambiguous language that appears throughout the Hatch-Waxman Amendments as a trigger for determining the applicability of statutory rights. Respondent now apparently considers it more important that there is no administrative conflict than that the intent of Congress is being disregarded. This is unacceptable. And it is precisely the type of mistake that Respondent and the court of appeals have made in this case—believing that Congress does not enact legislation, but merely makes suggestions that other branches of government are free to disregard when they choose.

CONCLUSION

The Petition For Certiorari should be granted.

Respectfully submitted,

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